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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,718	01/09/2007	Carl T Brighton	UPN-4914	4352

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EXAMINER	
KETTER, JAMES S	

ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,718	BRIGHTON, CARL T	
	Examiner	Art Unit	
	James S. Ketter	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,16-26,29 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *24,25 and 31* is/are allowed.

6)☒ Claim(s) *1-13,16-23,26 and 29* is/are rejected.

7)☒ Claim(s) *2, 13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Upon reconsideration of the claims, the following new grounds of rejection are presented, the delay in which is regretted.

Claims 2 and 13 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The instant claims, as they encompass variants of several of the recited parameters of the parent claim, would encompass some of said parameters outside of the ranges in the parent claim, and thus present a broader scope.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16-21, 26 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Brighton et al. (cited as "67" on the IDS filed 13 February 2007).

The instant claims are drawn to a device which comprises a signal source connected to electrodes or a coil, wherein the signal source controls and varies the duration or duty cycle of at least one signal for application to tissue in a patient, which signal creates a field which modulates BMP-2 mRNA.

Brighton et al. teaches, e.g., at the paragraph bridging pages 10 and 11, a device "capable of applying specific and selective signals directly to diseased or injured tissue and/or to the skin of a patient. The devices of the present invention may also provide for the remote application of specific and selective signals (e.g., application of a signal at a distance from diseased or injured tissue), although it will be appreciated that capacitively coupled devices must touch the subject's skin. The devices of the present invention may include means for attaching the electrodes to the body of a patient in the vicinity of injured or diseased tissue."

Claims 16-21, 26 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Dugot (cited as "45" on the IDS filed 13 February 2007).

The instant claims are drawn to a device which comprises a signal source connected to electrodes or a coil, wherein the signal source controls and varies the duration or duty cycle of at least one signal for application to tissue in a patient, which signal creates a field which modulates BMP-2 mRNA.

Dugot teaches, e.g., at the Abstract, a device that has a portable housing, which comprises a signal generator which supplies a periodically varying treatment signal to the patient, including as disclosed in the paragraph bridging columns 2 and 3, a compound electric signal comprising a 60 kHz sine wave having a peak to peak voltage of approximately 4.6 V to 7.6 V; and means for communicating said compound electric signals to a capacitive and/or inductive coupling device. The duty cycle, i.e., timing of the signal may be controlled. See, e.g., column 1, lines 33-48. Voltage per centimeter is merely a function of electrode placement. As such, the device of Dugot can inherently produce the recited signal, and therefore anticipates the instant claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 13, 22 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> A written description of an invention involving a chemical genus, like a description of a chemical species, "requires a precise definition, such as by structure, formula, [or] chemical name," of the claimed subject matter sufficient to distinguish it from other materials. *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus …") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not a sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include: (1) Actual reduction to practice, (2) Disclosure of drawings or structural chemical formulas, (3) Sufficient relevant identifying characteristics (such as: i. Complete structure, ii. Partial structure, iii. Physical and/or chemical properties, iv. Functional characteristics when coupled with a known or disclosed, and

correlation between function and structure), (4) Method of making the claimed invention, (5) Level of skill and knowledge in the art, and (6) Predictability in the art.

"Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case are discussed below.

In the instant case, the claims are drawn to a genus of methods, employing a genus of specific and selective signals that up-regulate expression of the BMP-2 gene. The signals used in claims 2 and 13 have been varied in an unlimited fashion except in that the BMP-2 must be up-regulated. The signals used in claims 22 and 23 are defined in that they may be produced by the device of claim 21, and that BMP-2 must be up-regulated. However, the device is not limited to producing only the signals encompassed in claim 21, but could produce signals having essentially any values for the signal parameters.

Practice of the claimed methods of treatment would have required that the characteristics of the "specific and selective electric or electromagnetic field" would have been known, including not just voltage and current, but also other factors such as length of exposure and duty cycle of the exposure. However, said characteristics beyond those in the ranges disclosed in the specification were not available to one of skill in the art. Furthermore, it is not clear what relationship the characteristics of the electric or electromagnetic field has to the disclosed effect, i.e., treatment of diseased tissue. Stated otherwise, there is no theory, algorithm or functional relationship presented either in the disclosure of the instant application or in the prior art, which

would have permitted one of skill in the art to have determined a priori what characteristics of the electric or electromagnetic field would function to treat diseased tissue as disclosed. The claims potentially encompass a virtually infinite set of possible characteristics of the fields, but only a relatively narrow set of characteristics are actually set forth in the specification. As such, an adequate written description of said characteristics, and therefore of the claimed invention, has not been presented.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13, 16-23, 26 and 29 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 7, 16 and 29, and therefore claims 2-6, 8-13, 17-23 and 26 which depend therefrom, recite "predetermined duration". However, this phrase is of unclear meaning, as it would not be apparent to one of skill in the art if the method were employing a predetermined duration or a randomly-determined duration. As such, the metes and bounds of the claims would be unclear.

Claims 2 and 13 recite "the gene expression of BMP-2…is substantially increased." However, it is not clear what degree of increase is "substantial", as it is a relative term. Furthermore, does claim 1, from which claim 2 depends, encompass insubstantial increases?

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James S. Ketter whose telephone number is 571-272-0770. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSK
23 February 2010

/James S. Ketter/
Primary Examiner, Art Unit 1636